

5

We Claim:

1 A nucleic acid sequence encoding a p63 cell regulatory protein, wherein said nucleic acid hybridizes under stringent conditions to a nucleic acid of SEQ ID Nos: 1-12, wherein said p63 cell regulatory protein binds a target DNA sequence.

10

Claim 2. A method for diagnosing malignant carcinomas, comprising:

- Sub B1
- (a) obtaining a biopsy sample of tissue;
 - (b) determining the level of a p63 gene product in said sample;
 - (c) comparing the level of said p63 gene product in said biopsy sample with the level of said p63 gene product in a control sample of cells;

15

wherein a decrease in the level of said p63 gene product is indicative of malignant carcinomas in said biopsy sample.

20

Ab 27

Claim 3. A method of claim 2, wherein said malignant carcinoma is carcinoma of the cervix, breast, salivary gland and/or prostate gland.

25

Sub B1

Claim 4. A method of claim 2, wherein said control sample is selected from the group comprising basal epithelial cells, immature squamous cells, ME 180 and human foreskin keratinocytes.

Ab 27

Claim 5. A method of claim 2, wherein the level of said p63 gene product is determined by a method selected from the group comprising RT-PCR, immunoblotting, immunoprecipitation, and sandwich immunoassay.

30

Sub B3

Claim 6. A method for detecting the onset of cancer in tissues containing sub-columnar reserve cells, comprising:

- (a) obtaining a biopsy sample of said tissue;
- (b) determining the level of a p63 gene product in said sample;
- (c) comparing the level of said p63 gene product in said biopsy sample with the level of said p63 gene product in a control sample of cells;

Sub B3
wherein a decrease in the level of said p63 gene product is indicative of the onset of cancer in said tissues.

10 Claim 7. A method of claim 6, wherein said tissue containing sub-columnar reserve cells is selected from the group comprising cervical tissue, breast tissue, and/or prostate gland tissue.

Sub C27
15 Claim 8. A method of claim 6, wherein said tissue containing sub-columnar reserve cells is selected from the group comprising kidney, testis, adrenal gland, brain, spleen, and thymus.

20 Claim 9. A method of claim 6, wherein said control sample is selected from the group comprising basal epithelial cells, immature squamous cells, ME 180 and human foreskin keratinocytes.

25 Claim 10. A method for distinguishing cervical squamous carcinoma from cervical small cell undifferentiated carcinoma, comprising:

- Sub B4
(a) obtaining a biopsy sample of tissue;
(b) determining the level of a p63 gene product in said sample;
(c) comparing the level of said p63 gene product in said biopsy sample with the level of said p63 gene product in a control sample of cells;

wherein a decrease in the level of said p63 gene product is indicative of small cell undifferentiated carcinoma.

30 Claim 11. A kit for diagnosing malignant carcinoma comprising:

- (a) a sample collecting means; and
(b) a p63 PCR primer pair.

Claim 12. A kit of claim 11, wherein said primer pair is selected from the group comprising TAp63-specific primer pair and a Δ Np63-specific primer pair.

an

Ante

ing ma
, where
dy and

Add